



**[BILLING CODE 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request**

**Population Assessment of Tobacco and Health (PATH) Study**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**PROPOSED COLLECTION:** *Title:* Population Assessment of Tobacco and Health (PATH)

*Study. Type of Information Collection Request:* NEW. *Need and Use of Information Collection:*

This is a large national longitudinal cohort study on tobacco use behavior and health in the United States. It is scheduled to begin in the fall of 2013 under the direction of the National Institutes of Health (NIH) National Institute on Drug Abuse (NIDA), and in partnership with the Food and Drug Administration (FDA). Using annual interviews and the collection of bio-specimens from adults, the study is designed to establish a population-based framework for monitoring and evaluating the behavioral and health impacts of regulatory provisions by FDA as it meets its mandate under the Family Smoking Prevention and Tobacco Control Act (FSPTCA) to regulate tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. These regulatory changes are expected to influence tobacco-product risk perceptions, exposures, and use patterns in the short term, and to reduce tobacco-related morbidity and

mortality in the long term. By measuring and accurately reporting tobacco product use behaviors and health effects associated with these regulatory changes, this study will provide an empirical evidence base to inform the development, implementation, and evaluation of tobacco-product regulations in the U.S.

*Frequency of Response:* Annually. *Affected Public:* Individuals or households. *Type of Respondents:* Youth (ages 12-17) and Adults (ages 18+). The annual reporting burden for the field test is presented in Table 1, and the annual reporting burden for the baseline data collection is presented in Table 2. The annualized cost to respondents for the field test is estimated at: \$24,495; and the annualized cost to respondents for the baseline data collection is: \$1,947,567. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**Table 1 PATH Study Field Test Hour Burden Estimates**

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Adults – Household Screener	1,295	1	22/60	479
Adults – Individual Screener	840	1	6/60	84
Adults – Extended Interview	590	1	1 26/60	844
Adults – Tobacco Use Form	590	1	2/60	18
Youth – Extended Interview	100	1	55/60	92
Adult – Parent Interview	100	1	24/60	40
Total	3,515	1		1,557

**Table 2 PATH Study Baseline Hour Burden Estimates**

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Adults – Household Screener	100,983	1	22/60	37,364
Adults – Individual Screener	63,000	1	6/60	6,300
Adults – Extended Interview	42,730	1	1 26/60	61,104
Adults – Tobacco Use Form	42,730	1	2/60	1,282
Youth – Extended Interview	16,857	1	55/60	15,508
Adult – Parent Interview	16,857	1	24/60	6,743
Total	283,157	1		128,301

**REQUEST FOR COMMENTS:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Blvd., Room 5185; 301-443-8755; email [PATHprojectofficer@mail.nih.gov](mailto:PATHprojectofficer@mail.nih.gov).

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Signed \_\_\_\_\_  
Helio Chaves  
Deputy Executive Officer (OM Director), NIDA

Dated: May 11, 2012

[FR Doc. 2012-12017 Filed 05/17/2012 at 8:45 am; Publication Date: 05/18/2012]